

5774-01-MJA  
Application No. 09/674,819

### REMARKS

#### I. Status of the Application

This submission, which accompanies a Request for Continued Examination, responds to a Final office Action that was mailed on June 6, 2005. The original application was filed with claims 1-17. In response to a Restriction Requirement mailed August 29, 2001, Applicant amended claims 1 and 12 and added claims 18 and 19. In response to an Office action mailed February 6, 2002, which rejected all of the claims, Applicant amended claim 12, canceled claims 18 and 19, and added claims 20 and 21. A subsequent Final Office Action, which was mailed on November 1, 2002, maintained the rejection of claims 1-17, and rejected newly added claims 20 and 21. Applicant subsequently filed an RCE. In the submission that accompanied the RCE, Applicant amended claims 1-17, 20, and 21, and added claims 22-27. In response to an Office action mailed September 26, 2003, Applicant canceled claims 1-17 and 20-27 and added new claims 28-42. The case was transferred to a new Art Unit. Applicant subsequently responded to a Restriction Requirement/Election of Species mailed February 8, 2005. This paper amends claims 28 and 40 and cancels claims 29-34, 38, 39 and 42 without prejudice or disclaimer. Accordingly, claims 28, 35-37, 40, and 41 are currently under consideration in this application.

By action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

#### II. Amendment of Claims 28 and 41

This submission amends independent claims 28 and 41 so that they each recite propylene glycol as the humectant.

After Final Amendment/Required Submission for RCE—page 4 of 6

5774-01-MJA  
Application No. 09/674,819

### III. Rejection of Claims Under 35 U.S.C. §§ 102/103

The Office action rejected claims 28, 30 and 35-42 under 35 U.S.C. § 102(b) as allegedly being anticipated by Jao et al. (US 5,660,861). The Office action also rejected claims 28, 30, 35-37, 40 and 41 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Jao et al. and Giacini et al. (US 5,302,373 and rejected claims 28 and 35-42 as being unpatentable over Jao et al. and Robson et al. (US 4,126,684). Applicant respectfully submits that the claims of the present application are patentable over the cited references.

As noted above, Applicant has amended independent claims 28 and 41 so that they each recite propylene glycol as the humectant. None of the references applied in the final Office action expressly disclose solid compositions or methods for stabilizing such compositions, which comprise gabapentin or pregabalin or both gabapentin and pregabalin and propylene glycol. Therefore, Applicant submits that none of the references of record anticipate claims 28, 35-37, 40 and 41.

Furthermore, whether viewed alone or in combination, none of the references render claims 28, 35-37, 40 and 41 obvious. As described on pages 3 and 4 of the specification, pharmaceutical preparations containing gabapentin or similar 4-amino-3-substituted-butanoic acid derivatives are difficult to prepare because the active ingredient may undergo lactamization. As demonstrated in the examples, Applicant has discovered that the addition of certain humectants such as propylene glycol to solid compositions containing gabapentin or pregabalin will prevent lactam formation, i.e., will stabilize the solid composition.

This result is completely unexpected. None of the references even hint that humectants such as propylene glycol will stabilize formulations containing gabapentin or pregabalin. The references list a few humectants among many excipients. These excipients belong to many different classes and serve many different purposes in pharmaceutical formulations. For example, besides sorbitol, Jao et al. lists various "osmagents" including magnesium sulfate, magnesium chloride, potassium chloride, lithium chloride, potassium sulfate, sodium sulfate, urea, etc., which one of skill in the art

After Final Amendment/Required Submission for RCE—page 5 of 6

5774-01-MJA  
Application No. 09/674,819

would not classify as humectants. The references provide little guidance as to which excipients will or will not stabilize gabapentin or pregabalin. Thus, at most, the references represent an obvious to try rationale, which cannot render the claims obvious.

Furthermore, Applicant respectfully submits that nothing in Jao et al., Giacin et al. or the other cited references, would motivate one of ordinary skill in the art to modify Jao et al to include propylene glycol. As noted in the Office action, Giacin et al. describes liquid mouth washes which purportedly contain propylene glycol or sorbitol to add "body and a pleasant mouth feel." In contrast, Jao et al. describes solid osmotic dosage forms which are not retained in the mouth for any significant period, but are instead swallowed. Thus, a person of ordinary skill in the art would not be motivated to replace sorbitol with propylene glycol in order to improve the "body" and "mouth feel" of the solid osmotic dosage form in Jao et al. Therefore, Applicant respectfully requests withdrawal of the rejection and allowance of the pending claims.

#### IV. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the references of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant believes that any fees associated with the filing of the present amendment have been identified in a transmittal that accompanies this paper. However, if any fees are required in connection with the filing of this paper, and such fees have not been identified in the accompanying transmittal, please charge deposit account number 23-0455.

Respectfully submitted,

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After Final Amendment/Required Submission for RCE—page 6 of 6